



## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS-2020-0030]

#### State University of New York College of Environmental Science and Forestry; Availability of a Draft Environmental Impact Statement and Draft Plant Pest Risk Assessment for Determination of Nonregulated Status for Blight-Tolerant Darling 58 American Chestnut (*Castanea dentata*) Developed Using Genetic Engineering

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice of availability.

**SUMMARY:** We are advising the public that the Animal and Plant Health Inspection Service has prepared a draft environmental impact statement (EIS) and draft plant pest risk assessment (PPRA) evaluating the potential environmental impacts and plant pest risk that may result from the approval of a petition for nonregulated status for blight-tolerant Darling 58 American chestnut (*Castanea dentata*) from the State University of New York College of Environmental Science and Forestry. The trees have been developed using genetic engineering to express an oxalate oxidase enzyme from wheat as a defense against the fungal pathogen *Cryphonectria parasitica*, making Darling 58 American chestnut tolerant to chestnut blight. We are making the draft EIS and draft PPRA available for public review and comment.

**DATES:** We will consider all comments that we receive on or before [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to [www.regulations.gov](https://www.regulations.gov). Enter APHIS-2020-0030 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.

- **Postal Mail/Commercial Delivery:** Send your comment to Docket No. APHIS-2020-0030, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

The petition and any comments we receive on this docket may be viewed at Regulations.gov or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

**FOR FURTHER INFORMATION CONTACT:** Mr. Subray Hegde, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1238; (301) 851-3901; email: subray.hegde@usda.gov.

#### **SUPPLEMENTARY INFORMATION:**

##### Background

Under the authority of the plant pest provisions of the Plant Protection Act, as amended (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, "Movement of Organisms Modified or Produced Through Genetic Engineering," regulate, among other things, the importation, interstate movement, or release into the environment of organisms modified or produced through genetic engineering that are plant pests or pose a plausible plant pest risk.

The Animal and Plant Health Inspection Service (APHIS) issued a final rule, published in the *Federal Register* on May 18, 2020 (85 FR 29790-29838, Docket No. APHIS-2018-0034),<sup>1</sup> revising 7 CFR part 340. However, this petition (APHIS Petition Number 19-309-01p)<sup>2</sup> for a determination of nonregulated status is being evaluated in accordance with the regulations at

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<sup>1</sup>To view the final rule, go to [www.regulations.gov](http://www.regulations.gov) and enter APHIS-2018-0034 in the Search field.

<sup>2</sup>To view the petition, go to <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/petitions/petition-status>.

7 CFR 340.6 (2020), which were effective at the time it was received by APHIS on January 21, 2020.

APHIS received a petition from the State University of New York College of Environmental Science and Forestry (ESF) seeking a determination of nonregulated status for blight-tolerant Darling 58 American chestnut (*Castanea dentata*). The petition states that Darling 58 American chestnut is unlikely to pose a plant pest risk and, therefore, should not be regulated under APHIS' regulations in 7 CFR part 340.

According to our process<sup>3</sup> for soliciting public comment when considering petitions for determination of nonregulated status of regulated organisms, APHIS accepts written comments regarding a petition once APHIS deems it complete. On August 19, 2020, we announced in the *Federal Register* (85 FR 51008-51009, Docket No. APHIS-2020-0030) the availability of the blight-tolerant chestnut petition for public comment.<sup>4</sup> We solicited comments on the petition for 60 days to help us identify potential environmental and interrelated economic issues and impacts that APHIS should consider in evaluation of the petition. We received 4,320 comments on the petition from the academic sector, farmers, non-governmental organizations, nonprofit organizations, industry, tribes, and unaffiliated individuals.

As part of our evaluation of the petition and consideration of public comments, APHIS concluded that the proposed determination of nonregulated status has the potential to

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<sup>3</sup>On March 6, 2012, APHIS published in the *Federal Register* (77 FR 13258-13260, Docket No. APHIS-2011-0129) a notice describing our public review process for soliciting public comments and information when considering petitions for determinations of nonregulated status for organisms developed using genetic engineering. To view the notice, go to [www.regulations.gov](http://www.regulations.gov) and enter APHIS-2011-0129 in the Search field.

<sup>4</sup>To view the notice, supporting documents, and the comments that we received, go to [www.regulations.gov](http://www.regulations.gov) and enter APHIS-2020-0030 in the Search field.

significantly affect the quality of the human environment.<sup>5</sup> In a notice<sup>6</sup> published in the *Federal Register* on August 6, 2021 (86 FR 43160-43162, Docket No. APHIS-2020-0030), APHIS announced its intention to prepare an environmental impact statement (EIS) to conduct the level of detailed and rigorous environmental analysis to make an informed decision about the proposed determination of nonregulated status for Darling 58 American chestnut.

APHIS solicited public comment for a period of 30 days ending September 7, 2021, as part of its scoping process to identify issues to address in the draft EIS. We received a total of 3,964 public comments. Issues most frequently cited in public comments on the notice concerning Darling 58 American chestnut included the following:

- Potential for gene flow to wild relatives;
- Potential to spread and become invasive;
- Potential non-target impacts, specifically to beneficial fungi, the microbiome, mycorrhizal networks, and the forest ecosystem;
- Potential impacts to wildlife, including pollinators, and threatened and endangered species; and
- Potential human health impacts from consuming nuts as well as potential allergies from pollen.

The issues discussed in the draft EIS were developed by considering the public input from the *Federal Register* notice announcing the intention to draft an EIS. APHIS evaluated these issues to analyze the potential environmental impacts of a determination of nonregulated status for Darling 58 American chestnut and included a discussion of these issues in the draft EIS.

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<sup>5</sup>Human environment means comprehensively the natural and physical environment and the relationship of present and future generations of Americans with that environment. Impacts/effects include ecological (such as effects on natural resources, and on the components, structures, and functioning of affected ecosystems), aesthetic, historic, cultural, economic (such as the effects on employment), social, or health effects (see 40 CFR 1508.1).

<sup>6</sup>To view the notice and the comments we received, go to [www.regulations.gov](http://www.regulations.gov) and enter APHIS-2020-0030 in the Search field.

Therefore, in accordance with the National Environmental Policy Act (NEPA), APHIS' NEPA Implementing Procedures (7 CFR part 372), and 7 CFR part 340, APHIS is making available the draft EIS, as well as a draft plant pest risk assessment, for a 45-day public review and comment period. The draft EIS and draft PPRA are available as indicated under ADDRESSES and FOR FURTHER INFORMATION CONTACT above.

A notice of availability regarding the draft EIS will also be published by the Environmental Protection Agency in the *Federal Register*.

Done in Washington, DC, this 2nd day of November 2022.

**Anthony Shea,**

*Administrator,*

*Animal and Plant Health Inspection Service.*

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